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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,819	09/24/2003	Gerald Fredrickson	12013/49401	7313
26646	7590	10/25/2004	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			PARKER, FREDERICK JOHN	
			ART UNIT	PAPER NUMBER
			1762	

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/670,819

Applicant(s)

FREDRICKSON, GERALD

Examiner

Frederick J. Parker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12-21-04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 14-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Election/Restrictions

1. Confirmation of election of claims 1-13 without traverse is acknowledged and appreciated.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 37 (new) is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - Claim 37 is vague and indefinite because the use of “high” to describe the pressure of the gas fails to describe the intended pressure of the gas, the phrase “high pressure” is not defined in the specification (merely exemplified on page 6, 1-6), and would not have been ascertainable by the skilled artisan due to the relative nature of the term “high” as used.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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5. Claims 1-14, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al in view of Park et al.

The references are cited for the same reasons previously discussed, which are incorporated herein. Applicants arguments have been fully considered.

Applicants argue the rejections of the previous Office Action does not meet the criteria for a prima facie case of obviousness, specifically there is no suggestion or motivation to modify or combine the references so that all claim limitations are taught or suggested.

The Applicants recognize that Schwartz utilizes a coating method for stents using air suspension via low velocity nozzles, and Park teaches coating stents using air suspension (as also discussed in Schwartz) using an ultrasonic nozzle and vibration at lower velocities than an air-atomizing nozzle so as not to harm bioactivity (as stated in previous Office Action). Both references teach coating stents with polymers and drugs in solution. It is taught on col. 7, 2-14 of Schwartz that the coatings should allow for a controlled release rate of the drug, including long-term and/ or sustained release. The use of the atomizing process of Park produces high populations of fragmented micro-droplets [0045, 0133] and advantageously provides drug-containing polymer coatings on stents having beneficial controlled release properties [0130]. Thus, given the similarity of the overall processes of the references, one of ordinary skill would have been motivated to incorporate the ultrasonic low velocity atomized coating spray of Park in the process of Schwartz, given the suggestion on col. 7, 2-14, to better provide drug-containing polymer coatings on stents having controlled release properties, which is a direct effect of the low velocity atomized coating spray. Schwartz teaches in the Abstract the coating needs to have minimal defects, uniform thickness and mechanical properties. The Examiner points out that one

skilled in the art would have recognized that the descriptions of the fragmented micro-droplets produced by the atomizing process of Park would have provided coating improvements, e.g. minimal defects, uniformity, etc as sought by Schwartz, because the geometric packing of finer droplets/ particles leads to a more tightly packed coating, which would be more uniform in microstructure and would have contained smaller defects (thereby improving mechanical properties) than would coatings formed of larger droplets/ particles. Thus, the previous Office Action properly provided motivation for the combination of references, with the expanded explanation provided in response to Applicants' arguments.

As to the argument regarding the fluidizing flow of claim 3, the Examiner points out at least col. 2, 1-8, wherein the atomized particles dispersed in the air stream contacts and coats the stent, which meets the limitations of claim 3.

Applicants also cite the use of "hindsight reasoning" on bottom of page 10 to dispute the combination of references. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which **was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper.** See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, the reconstruction is entirely proper for the reasons detailed above, and the motivation provided would have been apparent to the skilled artisan.

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In view of the reasons above, dependant claims 2-13 are maintained for the same reasons in the previous Office Action and as above.

New claim 37 is rejected because, while the meaning of "high pressure" is indefinite, the Examiner points out the specification provides AS EXAMPLES pressures of >20 psi, especially 35 psi, which is encompassed by the range on col. 13, 21-23 of Schwartz. Park is apparently silent on the pressure range for coating stents; however, it is the Examiner's position that one skilled in the art would have modified pressure for a given application. Thus claim 37 is also obvious in view of the cited prior art.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

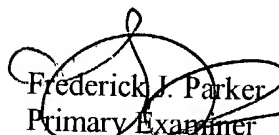
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick J. Parker whose telephone number is 571/ 272-1426. The examiner can normally be reached on Mon-Thur. 6:15am -3:45pm, and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive Beck can be reached on 571/272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Frederick J. Parker
Primary Examiner
Art Unit 1762

fjp